

Valley Medical Group, P.C.

Clinical Policy and Procedure

Title: Moderna COVID-19 Vaccine Management and Administration

Purpose: To ensure the safe storage and handling of the Moderna COVID-19 vaccine, in order to maintain optimum potency and efficacy, and to establish guidelines for the safe administration of the Moderna COVID-19 vaccine

Policy:

Moderna COVID-19 vaccine:

- Minimum order of 100 doses per carton.
- 10 dose multi-dose vial.
- Un-punctured vaccine can be stored at -15°C to -25°C until expiration date or it can be stored refrigerated at 2°C-8°C for 30 days.
- Once thawed, vaccine cannot be refrozen.
- Punctured/opened multi-dose vial must be used within 6 hours.
- Digital data loggers for continuous 24-hour temperature monitoring will be used to monitor temperature.

Procedure:

Moderna COVID-19 Vaccine will be stored in a dedicated, approved, vaccine freezer unit maintained at -15°C to -25°C, until expiration, or in a refrigerator designated for vaccine storage only, maintained at 2°C to 8°C for up to 30 days.

Digital data loggers for continuous 24-hour temperature monitoring will be used to monitor temperature. These data loggers will have a bio safe glycol-encased detachable temperature probe.

Vaccine Receiving

- Ensure that all staff that receives shipments (front office, loading dock, reception, etc.) are aware of the importance of notifying the RN Team Leader or designee as soon as the vaccine shipment arrives.
- Upon arrival at the health center, the box of vaccines will be opened immediately.
- The vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F)
- Examine the shipment for signs of damage
- Open the box and remove TagAlert Temperature Monitor from box (placed in the inner box next to vaccine)
- Check the TagAlert temperature monitoring device by pressing the blue “start and stop” button.
 - Left arrow points to a green checkmark: The vaccine is ready to use. Store the vaccine at proper temperatures immediately.
 - Right arrow points to a red X: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label DO NOT USE. Call the phone number indicated in the instructions or the MDPH Vaccine Management Unit @ (617) 983-6828 **immediately** for guidance.

- Ensure that all containers noted on the packing list have been delivered.
- If there are any concerns or inaccuracies with the vaccine order the RN Team Leader or designated staff will contact the MDPH Vaccine Management Unit @ (617) 983-6828 **immediately** for guidance.
- Once an inventory is completed, the vaccine is immediately placed in the refrigerator/freezer designated for vaccine storage only.

Vaccine Storage

- All refrigerators/freezers designated for vaccine storage will be set to maintain the proper temperature. Using a calibrated Fridge-tag 2 data logger, all vaccine storage units will have continuous temperature monitoring. Please contact the Vaccine Unit @617-983-6828 to report **ALL** temperature excursions.
- Moderna COVID-19 Vaccine will be stored in a dedicated, approved, separate freezer unit maintained at -15°C to -25°C, until expiration or in a refrigerator designated for vaccine storage only, maintained at 2°C to 8°C for up to 30 days.
- Vials that have not been punctured may be kept between 8°C and 25°C (46°F and 77°F) for up to 12 hours
- Use vaccine within 6 hours after vial is first punctured
- When thawed, the vaccine should be handled with care and protected from shocks, drops, vibration, etc.
- Please see Vaccine Management policy for complete storage guidelines for all state vaccines.

Temperature Monitoring

- Digital data loggers for continuous 24 hour temperature monitoring will be used to monitor temperature.
- The temperatures in the vaccine storage units should be monitored at least twice daily. When recording the temperature twice daily, press the READ key on the logger. This will be documented as AM and or PM when you print your monthly report. By pressing READ again on the device, it will display the warmest temperature for that day. By pressing READ again, it will display the coldest temperature for that day. Pay attention to the temperatures and report any out of range temperatures to the vaccine unit as soon as they are identified.
- The following information must be recorded on temperature log:
 - Minimum and Maximum Temperature
 - Date/Time
 - Initials of person checking and recording temperatures
 - Actions taken if a temperature excursion occurred
- Temperature logs must be retained for at least 3 years.
- Any deviations from recommended temperature ranges need to be reported as soon as they are identified to the Vaccine Management Unit at 617-983-6828.
- When a problem is discovered, the exposed vaccine is maintained at proper temperature and marked “Do Not Use” in a brown paper bag.
- Vaccine Management Unit will determine if the vaccine is still viable for use
- RN Team leader or designee must review temperature logs at least once a week for completeness.

Vaccine Transportation Procedures

Redistribution of vaccine may be required in some instances. Prior to redistribution, preferably 24 hours, providers should email the COVID-19 Vaccine Transfer form to the Vaccine Management Unit. Based on information to date from the manufacturer, for the Moderna COVID-19 Vaccine, the following general principles for vaccine redistribution should be considered:

Transportation when thawed

- Punctured vials should not be transported.
- Care must be taken to ensure vaccine does not re-freeze during transport.
- Vaccine must be protected as much as possible from drops, shocks, and vibration whether in the carton, vial, case or cooler.
- Vaccine should be transported in the carton whenever possible.
- If transport must be conducted at the vial level, the vial should be placed with padding material like bubble wrap to minimize movement during transport.
- Transport in insulated containers qualified to maintain 2-8°C for the duration of transport.
- Secured transport containers to prevent unnecessary movement.
- Vaccine being transported at temperatures other than frozen (-15°C to -25°C) should begin with the vaccine in the frozen state, if at all possible.
- Allowable timelines for transport of thawed vaccine are shown below. Total transport time should not exceed 12 hours in total.
 - Transport while walking or using hand cart: not to exceed 1 hour
 - Vehicle transport: not to exceed 12 hours

Receiving

- Upon receipt, confirm vaccine temperature and store vaccine at appropriate temperatures.
- Vaccine should only be transported one time and should not be transported back again to the point of origin or to a new location.

Vaccine Administration

- In preparation for administration, remove the required number of vials from frozen storage and thaw each vial before use:
 - Thaw in refrigerated conditions between 2°C to 8°C (36°F to 46°F) for 2 hours and 30 minutes and then room temperature for 15 minutes before administering.
 - Alternatively, thaw at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour
 - After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **DO NOT SHAKE.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Each dose is 0.5 mL

- Authorized age group is ≥ 18 years
- Moderna COVID-19 vaccine is not interchangeable with any other COVID-19 vaccine
- After the first dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F).
- Record the date and time for first use on the vial label. Discard vial after 6 hours. Do not refreeze.
- Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 28 days apart.
- Visually inspect each dose of the Moderna COVID-19 vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particles.
- During the visual inspection:
 - Verify the final dosing volume of 0.5 mL
 - Confirm there are no other particulates and that no discoloration is observed.
 - Do not administer if vaccine is discolored or contains other particulate matter.
- Prior to administration, all recipients must complete consent and screening form.
- Screening for contraindications and precautions MUST occur at every immunization encounter (not just before the first dose).
- An EUA Fact sheet must be given to all recipients.
- A copy of the V-Safe information form should be given to all recipients
- Vaccine administration team to include at least one provider (must be CPR certified), one vaccinator and one observer/documenter. Another member of the team should be CPR certified.
- Emergency supplies (Epinephrine, Benadryl etc.) must be at vaccine clinic location in order to respond to an emergency based on established guidelines
- Administer vaccine based on established guidelines
- Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.
- Recipient to remain in clinic area for observation after receiving vaccine for:
 - 30 minutes for persons with a history of any immediate allergic reaction to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines or polysorbate, as those are contraindicated)
 - 30 minutes for persons with a history of anaphylaxis (due to any cause)
 - 15 minutes for all other persons.
- Record each vaccine administered in the patient's chart including: expiration date (if there is one), type of vaccine, manufacturer, lot number, date on EUA and date EUA is given.
- Vaccine administration must be documented in recipient's medical record within 24 hours of administration and reported in the MIIS as soon as practicable and no later than 72 hours after administration

Equipment/Supplies:

- 25" gauge needles 1 to 1.5 inch
- 1 mL syringes
- Alcohol Wipes
- Band-aids
- Hand Sanitizer
- Sharps Container

- Appropriate PPE (masks, face shield or goggles, gloves)
- Timers
- Pens
- Wipes
- Consent/Screening forms
- EUA Fact sheet
- V-Safe information sheet
- Vaccination cards
- Epinephrine
- Benadryl
- Blood Pressure Cuff
- Stethoscope
- Timing device for assessing pulse

References:

Dosing & Administration / Moderna COVID-19 Vaccine (EUA) ([modernatx.com](https://www.modernatx.com))

Massachusetts Department of Public Health / [mass.gov/dph](https://www.mass.gov/dph)

CDC COCA Call, 12/30/2020, COVID-19 Vaccines: Update on Allergic Reactions, Contraindications, and Precautions: Tom Shimabukuro, MD, MPH, MBA and Sarah Mbaeyi, MD, MPH

Author: Rachel Bergstrom, RN

Approved by: Gina Campbell, MSN, RN, Vice President, Clinical Operations

Approved on: January 14, 2021

Effective Date: January 14, 2021